

**R**ISK UPDATES is a periodic bulletin prepared by EPA - Region I, New England risk assessors to provide information on new regional guidance. Risk Updates is distributed to contractors supporting Superfund and RCRA, regulators, and interested parties. Risk assessment questions may be directed to the following EPA scientists (area code 617):

Regional Risk Assessment Contact  
Ann-Marie Burke 223-5528

Superfund  
Human Health Risk Assessment  
Ann-Marie Burke 223-5528  
Sarah Levinson 573-9614  
Margaret McDonough 573-5714  
Jayne Michaud 223-5583

Ecological Risk Assessment  
Susan Svirsky 573-9649  
Patti Tyler 860-4342

RCRA Corrective Action  
Mary Ballew 573-5718  
Stephanie Carr 223-5593

Air Modeling  
Brian Hennessey 565-3572  
Combustion Risk Issues  
Jui-Yu Hsieh 565-3501  
Comparative Risk  
Katrina Kipp 565-3520  
Cost Benefit Analysis  
Ronnie Levin 565-9351  
Drinking Water  
Maureen McClelland 565-3543  
Air Risk Issues  
Jerri Weiss 565-9448

ORD Technical Liaison  
Ruth Bleyler 573-5792

EPA Region I, New England receives additional ecological technical support from Ken Finkelstein (223-5537) of the National Oceanic Atmospheric Administration (NOAA), and US Fish & Wildlife (Steve Mierzykowski 207/827-5938, Ken Munney 603/225-1411, and Tim Prior 401/364-9124).

Editors  
Stephanie Carr and Jayne Michaud  
Layout Gloria Hume

## Contents

EPA Ecological Guidance Update.....	Page 1
Superfund Risk Assessment Reform Initiatives.....	Page 2
Risk Characterization Update.....	Page 3
Mercury Update.....	Page 3
EPA Finalizes Soil Screening Guidance.....	Page 3
EPA's Proposed Cancer Guidance and Implementation Plan.....	Page 4
Ground Water Use and Value Guidance.....	Page 5
Lead Risk at CERCLA Sites and RCRA Correction Action Facilities.....	Page 6
Revised Manganese Reference Dose.....	Page 8
New Cancer Slope Factors for PCB's.....	Page 8

## EPA Ecological Risk Assessment Guidance Update

The EPA is in the process of finalizing two major ecological guidance documents. The first, Guidelines for Ecological Risk Assessment, is under development by the EPA Risk Assessment Forum (The Forum). The Forum was established to promote consensus on risk assessment issues, as defined in the 1983 Report of the National Research Council, and to ensure that this consensus be incorporated into Agency risk

assessment guidance. The Forum consists of risk assessment experts from throughout the Agency, including Region I. The final version of this document will expand upon the work presented in the Framework for Ecological Risk Assessment. The Guidelines will provide more direction for the various programs in EPA to follow when conducting ecological risk assessment and promise to be a particularly valuable tool in understanding the role of ecological risk assessment in the Superfund process. The Notice of Availability and Opportunity to Comment on Proposed Guidelines was published in the Monday, September 9, 1996 Federal Register (Vol. 61, No.175, page 47552). A copy can be obtained from the National Technical Information Service (703/487-4650) for \$47, or from the EPA home page: <http://www.epa.gov/ord/webpubs/fedreg>.

The second document which is being developed by the EPA Environmental Response Team is entitled Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments. This document provides a "hands-on" approach for conducting an ecological risk assessment and gathering the data to support such an assessment. This guidance loosely follows the Risk Assessment Forum approach.

Both of the documents described above are supplements to existing ecological guidance and do not replace existing guidance. EPA New England will issue regional guidance explaining how these two guidance documents should be

used in the Superfund program. This is tentatively scheduled for fall of 1996, depending upon the progress with the national guidance.

Two new Eco Updates were recently released by the EPA Office of Emergency and Remedial Response and can be found on the EPA home page.

- Ecotox Thresholds (EPA 540/f-95/038)
- Ecological Significance and Selection of Candidate Assessment Endpoints (EPA 540/f-95/037).

The Ecotox Thresholds bulletin provides an overview of the development and use of ecotox benchmark values in Superfund ecological risk assessments. The "Endpoints" bulletin provides guidance to risk assessors and managers in the selection of appropriate assessment endpoints for ecological study. Currently under development are Eco Update bulletins describing the screening process and how to use ecotox benchmarks correctly, and bioaccumulation of contaminants.

written by Susan Svirsky

---

---

## Superfund Risk Assessment Reform Initiatives

---

Specific areas of the Superfund risk assessment process were identified by the Superfund Administrative Reforms Initiative announced in 1995. Two EPA workgroups are currently addressing the risk assessment reform requirement to ensure reasonable and consistent risk assessments. The respective goals of these workgroups are:

- To establish national criteria to plan, report, and review risk assessments; and
- To revise Risk Assessment Guidance for Superfund (RAGS).

The first work group is tasked with establishing national criteria for the review, approval, and reporting of Superfund risk assessments. The products of this work group will also address the four core values of EPA Administrator Carol Browner's Risk Characterization Policy and Guidance Memorandum of transparency, clarity, consistency, and reasonableness (refer to Risk Characterization Update on the next page). To date, the work group has drafted a standard statement of work for risk assessments, standard risk assessment reporting tables, and a risk assessment data quality assurance checklist. The EPA work group has also solicited and received stakeholder input on these draft documents.

The RAGS Reform Work Group has developed a list of key

technical focus areas where the Superfund program would most benefit with respect to improving risk assessment and its application to Superfund, and also responds to critics of the program. The focus areas are toxicity assessment, exposure assessment, and risk communication. Two stakeholder dialogue meetings have been planned for late October and early November with representatives of the community, public, and private sector stakeholder groups. The goal of these meetings is to receive stakeholder input on which issues EPA should focus resources when revising and updating RAGS.

In Region I, preliminary stakeholder advisory opinions were obtained earlier this year at an EPA Federal Facilities Risk Assessment meeting at which the Air Force, Army, Navy, contractors, and States were present. The following technical issues were ranked highest among the participants: background determination, use of the reasonable maximum exposure method in decision making, uncertainty/probabilistic analysis, and land and groundwater use. The upcoming stakeholder dialogue meetings will provide formal input into the RAGS Reform Initiative.

For more information on the Superfund Administrative Reforms Initiatives, please contact Ann-Marie Burke or Jayne Michaud.

written by Jayne Michaud

---

---

## Risk Characterization Update

---

In response to criticism that the EPA's risk assessments are often difficult to understand and communicate, EPA Administrator Carol Browner issued a memorandum on Risk Characterization on March 21, 1995. This memorandum presents policies and guidance to serve as "building blocks" for development of program specific and region specific policies and procedures for improving risk characterizations. This policy will provide a basis for greater clarity, transparency, reasonableness and consistency in risk assessments across Agency programs. To achieve clarity, risk assessments must clearly identify the purpose and scope of the assessment, and present its uncertainties, strengths and weaknesses, and assumptions. To achieve transparency, the decision-making process must clearly separate scientific or technically-based conclusions from those based on policy. To achieve reasonableness, the components of the risk assessment must be based on sound scientific information and reasonable judgement and be integrated into an overall conclusion. The implementation of this policy will improve overall consistency of risk assessments.

Region I has developed a plan for implementing this policy in the Risk Characterization Implementation Plan for Region I.

The plan describes risk assessments conducted by or for Region I and outlines the criteria that should be used to determine whether the four fundamental values presented above have been addressed. The Risk Characterization Implementation Plan for Region I was signed by John DeVillars, Regional Administrator, on October 24, 1996. Copies of the Administrator's March 21, 1995 memorandum and Region I's Implementation Plan are available from Jerri Weiss or Margaret McDonough.

written by Margaret McDonough

---

## Mercury Update

---

Combustion facilities or incinerators are potentially a large source of environmental mercury contamination. To reduce emissions of mercury and other hazardous air pollutants, the revised MACT standards proposed for hazardous waste combustion facilities were signed by EPA Administrator Carol Browner on March 20, 1996 under the joint authority of the Clean Air Act (CAA) and the Resource Conservation and Recovery Act (RCRA). The rules were proposed on April 19, 1996 (61 FR 17358) and are scheduled to be finalized by March, 1998.

The proposed MACT standards for mercury are 50 ug/dscm (micrograms per dry weight standard cubic meter) for hazardous waste incinerators and hazardous waste-burning cement

kilns, and 72 ug/dscm for hazardous waste-burning light weight aggregate kilns. Under this proposal, continuous emission monitors (CEMs) would be required for particulate matter and mercury.

The CAA 112(n)(1)(B) requires EPA to submit a study on the atmospheric mercury emissions to Congress (the Mercury Report). The release of this report to Congress has been delayed. EPA released the report to the Science Advisory Board (SAB) in the beginning of July. The SAB was asked to review the issues related to effects of methyl mercury on child development and to develop a process for evaluating new data that is forthcoming from two large epidemiological studies. This report will also address mercury speciation, atmospheric deposition, bioconcentration factors, and toxicity data which are important for meaningful quantitative risk assessments.

The EPA has made the Mercury Study SAB Review Draft Report to Congress (document number EPA-452/R-96-001) available through the National Technical Information Service (703/487-4650).

written by Jui-Yu Hsieh

---

## EPA Finalizes Soil Screening Guidance

---

EPA finalized the Soil Screening Guidance in April, 1996. This guidance provides methods for calculating site-specific soil screening levels (SSLs) which can be used to identify areas of a hazardous waste site which do not warrant further federal attention.

The SSL guidance is expected to help standardize and accelerate the evaluation and cleanup of contaminated soils at sites with a future residential land use.

SSLs are not national standards and alone do not trigger the need for response actions nor do they define “unacceptable” levels of contaminants in soils. The SSL Guidance contains 110 general soil values as well as a methodology for derivation of site-specific concentrations. If soil screening levels are exceeded, further assessment but not necessarily cleanup is generally warranted. The generic soil values and methodology are designed to protect against exposures resulting from soil ingestion, inhalation of particulates and ingestion of contaminated groundwater resulting from soil leachate.

Soil screening levels are limited in their application by the fact that 1) they do not address ecological threats and 2) they are only developed for a residential exposure scenario. EPA has issued the guidance in two parts:

1. Soil Screening Guidance: User's Guide (OSWER Directive 9355.4-23, PB96-963505). The User's Guide is designed for the EPA site manager or Regional Manager seeking to understand the basic concepts, approaches, and assumptions in the soil screening decision framework.
2. Soil Screening Guidance: Technical Background Document (TBD) (OSWER Directive 9355.4-17A, PB96-963502). The Technical Background Document provides a

comprehensive analysis of the technical and policy issues and choices.

In addition, an overview is provided in the Soil Screening Guidance: Fact Sheet (OSWER Directive 9533.1-14FSA, PB96-963501). An overview of the EPA's response to comments received during the public comment period is also available in the Soil Screening Guidance: Response to Comments (OSWER Directive 9355.4-22, PB96-963506). These can be purchased from the National Technical Information Service (703/ 487-4650).

written by Stephanie Carr

---

## EPA's Proposed Cancer Guidance and Implementation Plan

---

EPA released the Proposed Guidelines for Carcinogen Risk Assessment in April, 1996 for a 120-day public review and comment period. The proposed revisions to the guidelines are a result of extensive EPA and other federal and independent scientific reviews, as well as recommendations from the National Academy of Sciences 1994 report, Science and Judgement in Risk Assessment. The Proposed Guidelines are a revision of EPA's 1986 Guidelines for Carcinogen Risk Assessment (51FR 33992), and when final will replace the 1986 guidelines.

The Proposed Guidelines will allow scientists to provide more relevant and up-to-date information in cancer evaluations on dose-response, route of exposure, and chemical structure of regulated chemicals. The major changes in the Proposed Guidelines are summarized below:

- Mode of Action: Perhaps the most important aspect of the proposal is the emphasis on mode of action, which considers how a substance causes cancer. More emphasis on the mode of action is expected to reduce the uncertainty in describing likelihood of harm and in determining dose-response approaches.
- Three descriptors for classifying human carcinogenic potential:
  - 1) “known/likely”, 2) cannot be determined, and 3) not likelyreplace the six alphanumeric categories (A, B1, B2, C, D, E) in the 1986 guidelines. In addition, a weight of evidence narrative, targeted at the risk manager, is added. This narrative summarizes the key evidence for the classification and presents significant strengths, weaknesses and uncertainties of the contributing evidence.
- Biologically-based extrapolation model is the preferred approach for quantifying risk.
- Three default approaches - Linear, Nonlinear, or Both are provided. Curve fitting in the observed range would be used to determine the effective dose corresponding to the lower 95% limit on a dose associated with a 10%

response (LED<sub>10</sub>). The LED<sub>10</sub> would then be used as a point of departure for extrapolation to the origin as the linear default or for a margin of exposure discussion as the nonlinear default.

- Hazard characterization is added to integrate the Data Analysis of all relevant studies into one weight of evidence conclusion of hazard.
- Risk characterization is more fully developed by providing direction on how the overall conclusion and confidence of risk is presented to the risk manager. Descriptions of major default assumptions and criteria for departing from them are described.

Until the guidelines are final, EPA will continue to rely on existing assessments. Once they are final, EPA will assess existing cancer values considering new risk assessment methods, principles and data. Reevaluating all existing cancer values on EPA's Integrated Risk Information System (IRIS) database would be time and resource prohibitive; therefore, EPA has developed a prioritization process to ensure that agents which warrant reevaluation are given the highest priority.

A five-step process will be used for determining which chemicals should be reevaluated. 1. EPA publishes an annual Federal Register notice requesting candidates for reevaluation. 2. Candidates are submitted. 3. EPA reviews and prioritizes candidates. 4. Candidates that EPA selects are published in a Federal Register notice. 5. Reassessment takes place in the following fiscal year during which time chemicals are peer reviewed

and placed on IRIS.

It should be noted that pending finalization of the Proposed Guidelines, the principles and approaches of the Proposed Guidelines may be applied in part or in whole, on a case-by-case basis. The proposed process for using the new guidelines can be found in the Federal Register (61 FR 32799).

The Proposed Guidelines are available in the Federal Register (61 FR 17960). An electronic version is also available through EPA's Office of Research and Development home page on the Internet at <http://www.epa.gov/ORD>. To obtain a 3.5" disc in WordPerfect 5.1 format, contact: ORD Publications Technology Transfer and Support Division, National Risk Management Laboratory, USEPA, 26 W. Martin Luther King Drive, Cincinnati, OH 43268 Telephone: 513/560-7562; Fax: 513/569-7566.

Please provide your name, mailing address, document title and the following EPA number (EPA/600/P-921003(a)).

written by Ann-Marie Burke

---

## Ground Water Use and Value Guidance

---

EPA-Region I recently finalized a new guidance document entitled the Ground Water Use and Value Determination Guidance. This guidance combines the goals of two major regional initiatives, the Superfund Beneficial Reuse Initiative and the Comprehensive Ground Water Protection

Strategy. As part of the Superfund Beneficial Reuse Initiative, this guidance is intended to result in more informed and focused decision-making and more common-sense, cost-effective ground water cleanups which will facilitate the beneficial reuse of contaminated parcels. To accomplish these objectives, this guidance incorporates the resource-based considerations used in EPA's Comprehensive Ground Water Protection Strategy. Specifically, this guidance document establishes an approach for determining the relative "use" and "value" of site ground water resources and explains how this determination affects EPA-Region I ground water remedial decision making process.

The guidance is a good example of how EPA intends to provide more flexibility to the states. The six New England States have provided comments on this guidance and support the process and concepts it contains.

### Overview

The new Approach to Superfund ground water decision making will be as follows:

- The Approach will be implemented in States with EPA-endorsed Comprehensive State Ground Water Protection Programs or CSGWPPs, but only where such States have entered into a Memorandum of Agreement (MOA) with EPA-Region I concerning the implementation of the Approach;
- In states that have entered into an MOA for the implementation of this guidance, EPA-New England will no longer rely on the 1986 Draft EPA Guidelines for Ground Water Classification in setting goals for ground water remediation and in making decisions on the level of cleanup necessary;

- Instead, a site specific determination will be made on the relative "use" and "value" of the ground water. States will play a pivotal role in determining the relative "use" and "value" of site ground water and will seek input from local officials and the public, as appropriate;
- EPA-New England will utilize the Use and Value Determinations performed by the States, in establishing remedial action objectives and making ground water remedial action decisions.

#### Application of This Guidance

The Approach provided in this guidance will be considered at current and future sites in the pre-remedial or RI/FS stages, to the extent possible. This

guidance is for use by EPA-Region I and State Remedial Project Managers in scoping Remedial Investigations, conducting Risk Assessments, developing Remedial Action Objectives and identifying Remedial Alternatives. EPA-Region I does not intend to re-open remedy selection decisions based on this guidance. This guidance is for internal Agency use and contains no right, substantive or procedural, for any party.

#### Relationship To Risk Assessment

In performing the Human Health Risk Assessment for the site, exposure scenarios will generally be based on the generally allowed uses under the state ground water classification system. Risk assessors should not vary their existing risk assessment procedures as a result of this

policy, other than to consider exposures based on the state classification rather than the 1986 draft federal guidelines.

The Use and Value Determination prepared by the States may be discussed as part of the exposure assessment section of the Risk Assessment. In other words, the Use and Value Determination may be used to place the exposure scenarios in perspective.

If you have any questions on how this guidance should be applied or would like to receive a copy of the guidance document, please contact any one of the following staff: Lynne Jennings, (617) 573-9634; Margery Adams, (617)

565-3746; Audrey Zucker, (617) 565-3444.

written by Lynne Jennings

---

## Lead Risk at CERCLA Sites and RCRA Correction Action Facilities

---

EPA takes a multimedia approach to estimating the risk from exposure to inorganic lead at a hazardous waste sites. Risks to children exposed to lead are estimated by predicting blood lead levels using a pharmacokinetic model. Risks to adults are estimated through use of a slope-factor approach. These methods for estimating risks are described below.

Lead Risks for Children in a

#### Residential Setting

For sites with a current or future potential residential land use, the sensitive receptor should be a child. EPA's Integrated Exposure Uptake and Biokinetic (IEUBK) model estimates the risk to a child resident. It is not appropriate to use this model for the adult resident, an older child (i.e., ages 9-18), or the adult worker. For future residential exposure scenarios, only a child's exposure to lead need be evaluated since this is the most sensitive receptor.

The IEUBK is a software package designed to combine exposures from lead in air, water, soil, dust, diet, paint, and other sources with a pharmacokinetic model. The output is a predicted distribution of blood lead levels in a child or a population of children from 6 months to 7 years of age. From this distribution, the model calculates the probability that blood lead concentration of a child or population of children will exceed a selected level of concern (the default value is a blood lead level of 10 micrograms lead per deciliter of blood). The user can then explore an array of possible changes in exposure media that would reduce the probability of unacceptable risk to those populations.

The model allows the user to input site-specific values other than the concentration of lead in soil; i.e., the concentration of lead in household dust, air, or drinking water, or the bioavailability of lead. The model can also be used to develop cleanup goals for lead at a hazardous waste site. In cases where site-specific data are not available, the standard default exposure assumptions built into the model should be used. This will result in a cleanup goal of 400 mg/kg (ppm) for residential

soils. The model's default values are the basis for the risk screening value of 400 mg/kg recommended in the "Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities" (OSWER Directive #9355.4-12) and the EPA Soil Screening Guidance (Publication number 9355.4-23).

When presenting the IEUBK model results to EPA, the user should include: 1) the age of the child targeted; 2) site-specific parameter values; 3) standard defaults; and, 4) the percentage of children predicted to have blood leads above the EPA cutoff of 10 micrograms/deciliter. In the IEUBK computer model, the user should choose the graph for the probability density function and enter the appropriate parameters.

Both the IEUBK computer model (Pub. No. 9285.7-15-2; PB93-963511) and the guidance manual (Pub. No. 9285.7-15-1; PB93-963510) are available to the public through the National Technical Information Service (703/487-4650) or the EPA Region I Library (617/565-3300).

Lead Risks for Commercial or Industrial Workers and Youth Trespassers

The EPA Technical Review Workgroup for Lead (TRW) is conducting additional research on a biokinetic mode for adult exposures. The TRW consists of risk assessors, scientists, policy analysts, statisticians, and project managers including Region I representatives Margaret McDonough and Mary Ballew. As an interim approach, the TRW has recommended a simplified slope factor approach. The slope factor

approach is conceptually similar to that proposed by Bowers et al. (1994) which was adapted for use at the California Gulch NPL site in Region 8 (Weston, 1995).

On October 26, 1995, the TRW published a report, Review of a Methodology for Establishing Risk-Based Soil Remediation Goals for Commercial Areas of the California Gulch Site. The TRW has endorsed the slope factor approach presented in this report, as an interim method for evaluating the risks to adults exposed to lead. This fall, the TRW expects to release a more generic guidance document that will contain a clear method for calculating a preliminary remediation goal for an industrial or commercial exposure scenario and the rationale for each parameter used in this new approach. The TRW has emphasized the importance of collecting data to support site-specific parameter estimates, however, default parameter guidance will also be provided.

Preliminary calculations by the TRW suggest that the slope factor approach could be adapted for use in a trespasser scenario. Parameters should be adjusted to account for any age-related differences. It is appropriate to use the slope factor approach when trespassing frequency is equal to or greater than once per week over the course of a minimum duration of ninety days.

The 1995 California Gulch review report is available from the Region I library. The TRW report Methodology for Assessing Risks Associated with Adult Exposures to Lead in Soil will be available by the

end of 1996. A copy will be available at the Region I library 617/565-3300 or Toll Free at 800-EPA-LIBR.

written by Mary Ballew and  
Margaret McDonough

## References

Bowers et al. 1994: Bowers, TS, Beck BD, Karam HS. 1994. Assessing the relationship between environmental lead concentrations and adult blood lead levels. Risk Analysis 14:183-89.

Weston 1995: Roy F. Weston, Inc. 1995. Baseline human health risk assessment for the California Gulch Superfund site. February. Prepared for USEPA Region 8, Denver CO.

---

## Revised Manganese Reference Dose

---

The manganese reference dose (RfD) in the IRIS data base was revised in November, 1995. This revision results in a lower risk (and thus, higher cleanup level) for drinking water compared to the previous RfD. The IRIS RfD of 1.4E-1 mg/kg/day is for the total oral intake of manganese. As stated in the IRIS file, it is recommended that a modifying factor of 3 be applied to the RfD for non-dietary exposures.

### Background

Prior to November, 1995 the IRIS data base provided two reference doses for manganese, one for food and one for water. The food RfD was based on dietary intake of manganese. The water RfD was based on a study of humans who had ingested drinking water containing elevated levels of manganese as well as on assumptions regarding differences in absorption of manganese in food as opposed to water.

The drinking water RfD was withdrawn from IRIS in November, 1995 because of concerns about the validity of the human exposure study and because new information indicated that the disparity between absorption of manganese from food as opposed to water was overestimated.

### New Approach

The revised RfD for manganese is for the total oral intake of manganese. This value is 0.14 mg/kg/day and is derived as follows:

- 10 mg/day of manganese may be consumed without adverse effects (the "critical dose"). This value comes from several dietary studies.
- average adult body weight = 70 kg

Therefore, the RfD =

$$\frac{10 \text{ mg/day}}{70 \text{ kg}} = 0.14 \text{ mg/kg/day}$$

A modifying factor of 3 is recommended in IRIS when assessing exposure from drinking water.

### Drinking Water Exposures

The average dietary manganese content of the U.S. population, 5 mg/day, is subtracted from the "critical dose" of 10 mg/day:

$$10 \text{ mg/day} - 5 \text{ mg/day} = 5 \text{ mg/day}$$

Apply modifying factor of 3 per IRIS recommendation:

$$\frac{5 \text{ mg/day}}{3} = 1.67 \text{ mg/day}$$

Compute RfD:

$$\frac{1.67 \text{ mg/day}}{70 \text{ kg}} = .024 \text{ mg/kg day}$$

The Hazard Index (HI) for drinking water is calculated as follows (using a simplified equation):

$$\frac{\text{Concentration(mg/L)} * 2\text{liters/day}}{0.024 \text{ mg/kg/day} * 70 \text{ kg}}$$

A HI of 1 corresponds to a concentration of 840 ug/L.

### Soil Exposure

A modifying factor of 3 may be appropriate for assessing risks via exposure to soils if neonates (a child 12 months or younger) are a potentially exposed population. For most RCRA and Superfund risk assessments neonates are unlikely to be exposed to significant amounts of soils. Therefore, a modifying factor of 1 is appropriate. Assuming exposure to a young child under a residential scenario, a hazard index of 1 for manganese in soil would correspond to a soil concentration of 5,500 mg/kg.

written by Margaret McDonough

---

## New Cancer Slope Factors for PCBs

---

EPA recently reassessed the scientific evidence for the carcinogenicity of polychlorinated biphenyls (PCBs). A range of new cancer slope factors for PCB mixtures were posted on the IRIS chemical information data base on October 1, 1996. The new slope factors reflect the current knowledge of EPA scientists and national experts concerning:

- the influence on toxicity of PCBs by chemical transformation in the environment;
- the tendency of PCBs to partition into various media; and
- the potential for PCBs to biomagnify through the food chain.



To fully understand the scientific basis for the slope factors and to correctly apply them in a risk assessment, carefully read EPA's supporting technical document, PCBs: Cancer Dose-response Assessment and Application to Environmental Mixtures, which explains in greater detail the basis for the PCB reassessment.

The PCB reassessment results in different cancer slope factors for PCB mixtures based on a consideration of several different factors. First, the reassessment recognizes that environmental processes may significantly change the toxicity of Aroclor mixtures released into the environment. Thus, new slope factors are determined by the environmental pathway of exposure rather than by reference to a toxicity study for the particular Aroclor. Second, toxicity studies which formed the basis of the previous slope factor for PCBs were reanalyzed using new criteria and nomenclature for rat liver tumors, which resulted in a reduced number of tumors reported for Aroclor mixtures. Third, new PCB toxicity studies, sponsored by the General Electric Company, were considered in the derivation of the new cancer slope factors. Fourth, a revised cross-species scaling factor as recommended in EPA's Proposed Guidelines for Carcinogen Risk Assessment, 61FR 17960, was incorporated into the derivation of the new slope factors. Lastly, a new method for extrapolating risk to low doses from experimental data as recommended in EPA's New Cancer Guidelines was utilized in deriving the new slope factors.

The reassessment

recommends a tiered approach for determining central tendency and high end cancer slope factors for use in risk assessment. When congener information is limited, the exposure pathway is used to indicate whether environmental processes have increased or decreased a PCB mixture's potency. When congener information is available, further refinement of the potency estimate can occur. Three categories of slope factors are developed based on the exposure pathway or, if more information is available, the PCB congener makeup of the mixture. A "high-risk" category is used for exposure pathways associated with environmental processes that tend to increase risk; a "low-risk" category for those that tend to decrease risk; and a "lowest risk" category for cases where congener or isomer analyses verifies the absence of congeners with more than 4 chlorines (establishing sufficient similarity of an environmental mixture to the least potent PCB Aroclor tested).

Additional highlights of the reassessment include the following:

- Changes in the types of environmental data collected for PCBs are recommended. At present, data are collected for the commercially available mixtures of PCBs (Aroclors) and the total amount of PCBs. The reassessment recommends collecting data on either the total amount of PCBs or on congeners (which represent up to 209 different arrangements of the chlorine atoms on the PCB molecule).

- Analysis of dioxin-like PCBs is recommended, if they are thought to be present. For samples containing dioxin-like PCBs, the risk of the dioxin-like PCBs is added to the risks calculated using the cancer slope factors for nondioxin-like PCBs presented in this reassessment. Only a congener-specific analysis can determine whether dioxin-like PCBs are present. The risks from dioxin-like PCBs are evaluated using a toxicity equivalence factor (TEF) approach, (See the PCB reassessment and March 1989 Interim Procedures For Estimating Risks Associated With Exposures to Mixtures of Chlorinated Dibenzo-p-dioxins and -Dibenzofurans (CDDs and CDFs) and 1989

Update (EPA/625/3-89/016) for more details.)

- c New highly exposed and highly sensitive populations who merit specific evaluation are identified. "Highly exposed populations include some nursing infants and consumers of game fish and game animals contaminated through the food chain. Highly sensitive populations include people with decreased liver function and infants."

The reassessment may produce changes in the way we investigate hazardous waste sites and estimate risks for PCBs. Lower estimates of risk from PCBs could result for several exposure pathways. When assessing the risks from PCB mixtures, please contact a Region I risk assessor.

The PCB reassessment is available on the Office of

Research and Development home page on the Internet at <http://www.epa.gov/ORD>. A copy is also available at the Region I EPA library and it may be copied onto a disk if you bring your own. The library has a new toll free number for calls within New England: 888-EPA-LIBR.

written by Mary Ballew  
& Ann-Marie Burke

---

To be included on future mailing list,  
please send your address including  
Internet address to: Jayne Michaud  
or Stephanie Carr at:  
[michaud.jayne@epamail.epa.gov](mailto:michaud.jayne@epamail.epa.gov)  
[carr.stephanie@epamail.epa.gov](mailto:carr.stephanie@epamail.epa.gov)

USEPA - New England  
JFK Federal Building, HBT  
Boston, MA 02203